4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0450]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Abbreviated New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0669 and title "Abbreviated New Animal Drug Applications." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Abbreviated New Animal Drug Applications--Section 512(b)(2) and (n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(b)(2) and (n)(1)) (OMB Control Number 0910-0669)--Extension

On November 16, 1988, the President signed into law the Generic Animal Drug and Patent Restoration Act (GADPTRA) (Public Law 100-670). Under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by GADPTRA, any person may file an abbreviated new animal drug application (ANADA) seeking approval of a generic copy of an approved new animal drug. The information required to be submitted as part of an abbreviated application is described in section 512(n)(1) of the FD&C Act. Among other things, an abbreviated application is required to contain information to show that the proposed generic drug is bioequivalent to, and has the same labeling as, the approved drug referenced in the abbreviated application. FDA allows applicants to submit a complete ANADA or to submit information in support of an ANADA for phased review followed by the submission of an Administrative ANADA when FDA finds that all the applicable technical sections for an ANADA are complete. FDA requests that an applicant accompany ANADAs and requests for phased review of data to support ANADAs with the Form FDA 356v to ensure efficient and accurate processing of information to support approval of the generic new animal drug.

In the Federal Register of April 30, 2013 (78 FR 25279), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received; however the comment was not responsive to any of the four topics solicited by the notice. Therefore, FDA does not address the comment here.

FDA estimates the burden of this collection of information as follows:

Table 1.--ANADAs: Estimated Annual Reporting Burden

FD&C Act Section 512 (b)(2)	FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
ANADA	356v	18	1	18	159	2,862
Phased Review With Administrative ANADA	356v	3	5	15	31.8	477
Total						3,339

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

ANADA paperwork burden (section 512(b)(2) of the FD&C Act). Over the past 5 fiscal years, from October 2007 through September 2012, FDA has received an average of 21 ANADAs per year. FDA estimates that preparing the paperwork required under 21 U.S.C. 360b(n)(1) to be contained in an ANADA, whether all of the information is submitted with the ANADA or the applicant submits information for phased review followed by an Administrative ANADA that references that information, will take approximately 159 hours. (FDA is estimating that each ANADA that uses the phased review process will have approximately five phased reviews per application. Therefore, assuming that three respondents will take advantage of the phased review option per year and an average of five phased reviews are submitted per application, times 31.8 hours per phased review, equals 477 total hours per year or 159 hours per application.)

Although over the last 5 fiscal years all sponsors chose to submit traditional ANADAs, some sponsors did indicate an interest in using the phased review option in the future. FDA believes that, with time, more and more sponsors will take advantage of the phased review option as it provides greater flexibility and estimates that there will be three respondents for the phased review option. FDA also estimates that sponsors of ANADAs take approximately 25

percent less time to put together the information to support an ANADA than a new animal drug application (NADA) because they only need to provide evidence of bioequivalence and not the data required in a NADA to support a full demonstration of safety and effectiveness.

Form FDA 356v. FDA requests that an applicant fills out and sends in a Form FDA 356v with an ANADA, and with requests for phased review of data to support ANADAs, to ensure efficient and accurate processing of information to support the approval of a generic new animal drug.

Records and reports that are required post approval are described in 21 CFR 514.80, and that paperwork is already covered by that rule in OMB control number 0910-0284.

Dated: August 20, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

[FR Doc. 2013-20712 Filed 08/23/2013 at 8:45 am; Publication Date: 08/26/2013]